

## Environmental Protection Agency

## § 2.307

to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(d) of the Act (15 U.S.C. 2613(d)).

(k) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(a)(3) of the Act (15 U.S.C. 2613(a)(3)), any information to which this section applies may be disclosed by EPA when disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (k).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the General Counsel in writing of the nature of the unreasonable risk of injury, the extent of the disclosure proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the General Counsel, the EPA office shall notify the General Counsel orally.

(3) Upon receipt of notification under paragraph (k)(2) of this section, the General Counsel shall make a deter-

mination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The General Counsel shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the General Counsel determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the General Counsel shall furnish notice to each affected business of the contemplated disclosure and of the General Counsel's determination. Such notice shall be made in writing by certified mail, return receipt requested, at least 15 days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the General Counsel determines that the risk of injury is so imminent that it is impracticable to furnish such notice 15 days before the proposed date of disclosure, the General Counsel may provide notice by means that will provide receipt of the notice by the affected business at least 24 hours before the disclosure is to be made. This may be done by telegram, telephone, or other reasonably rapid means.

[43 FR 40003, Sept. 8, 1978, as amended at 44 FR 17674, Mar. 23, 1979; 58 FR 462, Jan. 5, 1993]

### **§ 2.307 Special rules governing certain information obtained under the Federal Insecticide, Fungicide and Rodenticide Act.**

(a) *Definitions.* For the purposes of this section;

(1) *Act* means the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*, and its predecessor, 7 U.S.C. 135 *et seq.*

(2) *Applicant* means any person who has submitted to EPA (or to a predecessor agency with responsibility for administering the Act) a registration

statement or application for registration under the Act of a pesticide or of an establishment.

(3) *Registrant* means any person who has obtained registration under the Act of a pesticide or of an establishment.

(b) *Applicability*. This section applies to all information submitted to EPA by an applicant or registrant for the purpose of satisfying some requirement or condition of the Act or of regulations which implement the Act, including information originally submitted to EPA for some other purpose but incorporated by the applicant or registrant into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. This section does not apply to information supplied to EPA by a petitioner in support of a petition for a tolerance under 21 U.S.C. 346a(d), unless the information is also described by the first sentence of this paragraph.

(c) *Basic rules which apply without change*. Sections 2.201 through 2.203, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Initial action by EPA office*. Section 2.204 applies to information to which this section applies, except that the provisions of paragraph (e) of this section regarding the time allowed for seeking judicial review shall be reflected in any notice furnished to a business under § 2.204(d)(2).

(e) *Final confidentiality determination by EPA legal office*. Section 2.205 applies to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel (or his designee), rather than the Regional Counsel, shall make the determinations and take the actions required by § 2.205;

(2) In addition to the statement prescribed by the second sentence of § 2.205(f)(2), the notice of denial of a business confidentiality claim shall state that under section 10(c) of the Act, 7 U.S.C. 136h(c), the business may commence an action in an appropriate Federal district court for a declaratory judgment;

(3) The following sentence is substituted for the third sentence of § 2.205(f)(2): “With respect to EPA’s im-

plementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the date of the business’s receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business’s commencement of an action in a Federal court to obtain judicial review of the determination or to obtain a declaratory judgment under section 10(c) of the Act and to obtain preliminary injunctive relief against disclosure.”; and

(4) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (e)(3) of this section, shall not be shortened without the consent of the business.

(f) [Reserved]

(g) *Substantive criteria for use in confidentiality determinations*. Section 2.208 applies without change to information to which this section applies; however, no information to which this section applies is voluntarily submitted information.

(h) *Disclosure in special circumstances*. (1) Section 2.209 applies without change to information to which this section applies. In addition, under section 12(a)(2)(D) of the Act, 7 U.S.C. 136j(a)(2)(D), EPA possesses authority to disclose any information to which this section applies to physicians, pharmacists, and other qualified persons needing such information for the performance of their duties, notwithstanding the fact that the information might otherwise be entitled to confidential treatment under this subpart. Such authority under section 12(a)(2)(D) of the Act may be exercised only in accordance with paragraph (h)(2) or (h)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it might otherwise be entitled to confidential treatment under this subpart) to physicians, pharmacists, hospitals, veterinarians, law enforcement personnel, or governmental agencies with responsibilities for protection of public health, and to

employees of any such persons or agencies, or to other qualified persons, when and to the extent that disclosure is necessary in order to treat illness or injury or to prevent imminent harm to persons, property, or the environment, in the opinion of the Administrator or his designee.

(3) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act or regulations which implement the Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedure and requirements of § 2.301(h)(2) (ii) through (iv).

(4) Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee.

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

**§ 2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.**

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*

(2) *Petition* means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(d) of the Act, 21 U.S.C. 346a(d).

(3) *Petitioner* means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) *Applicability.* (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a

petitioner, solely in support of a petition which has not been acted on by the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of § 2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Effect of submission of information without claim.* Section 2.203 (a) and (b) apply without change to information to which this section applies. Section 2.203(c), however, does not apply to information to which this section applies. A petitioner's failure to assert a claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of a petitioner's claim, a petitioner shall be regarded as an affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA office acting under § 2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with § 2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under § 2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality